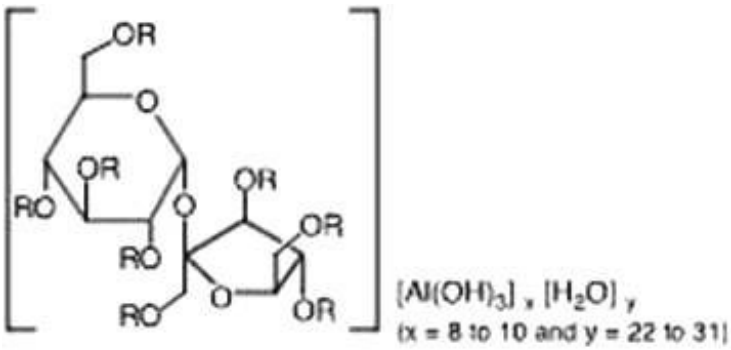
SUCRALFATE- sucralfate suspension
Cardinal Health

Sucralfate Suspension

Rx Only

DESCRIPTION

Sucralfate Suspension contains sucralfate, and sucralfate is an α-D-glucopyranoside, β-D-fructofuranosyl-, octakis-(hydrogen sulfate), aluminum complex.



R = $SO_3Al(OH)_2$

Sucralfate Suspension for oral administration contains 1 g of sucralfate per 10 mL.

Sucralfate Suspension also contains: colloidal silicon dioxide NF, FD&C Red No. 40, flavor, glycerin USP, methylcellulose USP, methylparaben NF, microcrystalline cellulose NF, purified water USP, simethicone USP, and sorbitol solution USP.

Therapeutic category: antiulcer.

CLINICAL PHARMACOLOGY

Sucralfate is only minimally absorbed from the gastrointestinal tract. The small amounts of the sulfated disaccharide that are absorbed are excreted primarily in the urine.

Although the mechanism of sucralfate's ability to accelerate healing of duodenal ulcers remains to be fully defined, it is known that it exerts its effect through a local, rather than systemic, action. The following observations also appear pertinent:

1. Studies in human subjects and with animal models of ulcer disease have shown that sucralfate forms an ulcer-adherent complex with proteinaceous exudate at the ulcer site.
2. In vitro, a sucralfate-albumin film provides a barrier to diffusion of hydrogen ions.
3. In human subjects, sucralfate given in doses recommended for ulcer therapy inhibits pepsin activity in gastric juice by 32%.
4. In vitro, sucralfate absorbs bile salts.

These observations suggest that sucralfate's antiulcer activity is the result of formation of an ulcer-adherent complex that covers the ulcer site and protects it against further attack by acid, pepsin, and bile salts. There are approximately 14 to 16 mEq of acid-neutralizing capacity per 1-g dose of sucralfate.

CLINICAL TRIALS

In a multicenter, double-blind, placebo-controlled study of Sucralfate Suspension, a dosage regimen of 1 g (10 mL) four times daily was demonstrated to be superior to placebo in ulcer healing.

Results From Clinical Trials Healing Rates for Acute Duodenal Ulcer				
Treatment	n	Week 2 Healing Rates	Week 4 Healing Rates	Week 8 Healing Rates
Sucralfate Suspension	145	23(16%)*	66(46%)†	95(66%)‡
Placebo	147	10(7%)	39(27%)	58(39%)

* *P*=0.016

† *P*=0.001

‡ *P*=0.0001

Equivalence of sucralfate suspension to sucralfate tablets has not been demonstrated.

INDICATIONS AND USAGE

Sucralfate Suspension is indicated in the short-term (up to 8 weeks) treatment of active duodenal ulcer.

CONTRAINDICATIONS

There are no known contraindications to the use of sucralfate.

PRECAUTIONS

Duodenal ulcer is a chronic, recurrent disease. While short-term treatment with sucralfate can result in complete healing of the ulcer, a successful course of treatment with sucralfate should not be expected to alter the posthealing frequency or severity of duodenal ulceration.

Special Populations

Chronic Renal Failure and Dialysis Patients

When sucralfate is administered orally, small amounts of aluminum are absorbed from the gastrointestinal tract. Concomitant use of sucralfate with other products that contain aluminum, such as aluminum-containing antacids, may increase the total body burden of aluminum. Patients with normal renal function receiving the recommended doses of sucralfate and aluminum-containing products adequately excrete aluminum in the urine. Patients with chronic renal failure or those receiving dialysis have impaired excretion of absorbed aluminum. In addition, aluminum does not cross dialysis membranes because it is bound to albumin and transferrin plasma proteins. Aluminum accumulation and toxicity (aluminum osteodystrophy, osteomalacia, encephalopathy) have been described in patients with renal impairment. Sucralfate should be used with caution in patients with chronic renal failure.

Drug Interactions

Some studies have shown that simultaneous sucralfate administration in healthy volunteers reduced the extent of absorption (bioavailability) of single doses of the following: cimetidine, digoxin, fluoroquinolone antibiotics, ketoconazole, l-thyroxine, phenytoin, quinidine, ranitidine, tetracycline, and theophylline. Subtherapeutic prothrombin times with concomitant warfarin and sucralfate therapy have been reported in spontaneous and published case reports. However, two clinical studies have demonstrated no change in either serum warfarin concentration or prothrombin time with the addition of sucralfate to chronic warfarin therapy. The mechanism of these interactions appears to be nonsystemic

in nature, presumably resulting from sucralfate binding to the concomitant agent in the gastrointestinal tract. In all cases studied to date (cimetidine, ciprofloxacin, digoxin, norfloxacin, ofloxacin, and ranitidine), dosing the concomitant medication 2 hours before sucralfate eliminated the interaction. Because of the potential of Sucralfate Suspension to alter the absorption of some drugs, Sucralfate Suspension should be administered separately from other drugs when alterations in bioavailability are felt to be critical. In these cases, patients should be monitored appropriately.

Carcinogenesis, Mutagenesis, Impairment of Fertility

Chronic oral toxicity studies of 24 months' duration were conducted in mice and rats at doses up to 1 g/kg (12 times the human dose). There was no evidence of drug-related tumorigenicity. A reproduction study in rats at doses up to 38 times the human dose did not reveal any indication of fertility impairment. Mutagenicity studies were not conducted.

Pregnancy

Teratogenic effects

Pregnancy Category B

Teratogenicity studies have been performed in mice, rats, and rabbits at doses up to 50 times the human dose and have revealed no evidence of harm to the fetus due to sucralfate. There are, however, no adequate and well-controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, this drug should be used during pregnancy only if clearly needed.

Nursing Mothers

It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when sucralfate is administered to a nursing woman.

Pediatric Use

Safety and effectiveness in pediatric patients have not been established.

Geriatric Use

Clinical studies of Sucralfate Suspension did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects. Other reported clinical experience has not identified differences in responses between the elderly and younger patients. In general, dose selection for an elderly patient should be cautious, usually starting at the low end of the dosing range, reflecting the greater frequency of decreased hepatic, renal, or cardiac function, and of concomitant disease or other drug therapy. (See DOSAGE AND ADMINISTRATION)

This drug is known to be substantially excreted by the kidney, and the risk of toxic reactions to this drug may be greater in patients with impaired renal function. (See PRECAUTIONS Special Populations: Chronic Renal Failure and Dialysis Patients) Because elderly patients are more likely to have decreased renal function, care should be taken in dose selection, and it may be useful to monitor renal function.

ADVERSE REACTIONS

Adverse reactions to sucralfate tablets in clinical trials were minor and only rarely led to discontinuation of the drug. In studies involving over 2700 patients treated with sucralfate, adverse effects were reported in 129 (4.7%).

Constipation was the most frequent complaint (2%). Other adverse effects reported in less than 0.5% of the patients are listed below by body system:

Gastrointestinal: diarrhea, dry mouth, flatulence, gastric discomfort, indigestion, nausea, vomiting

Dermatological: pruritus, rash

Nervous System: dizziness, insomnia, sleepiness, vertigo

Other: back pain, headache

Postmarketing reports of hypersensitivity reactions, including urticaria (hives), angioedema, respiratory difficulty, rhinitis, laryngospasm, and facial swelling have been reported in patients receiving sucralfate tablets. Similar events were reported with sucralfate suspension. However, a causal relationship has not been established.

Bezoars have been reported in patients treated with sucralfate. The majority of patients had underlying medical conditions that may predispose to bezoar formation (such as delayed gastric emptying) or were receiving concomitant enteral tube feedings.

Inadvertent injection of insoluble sucralfate and its insoluble excipients has led to fatal complications, including pulmonary and cerebral emboli. Sucralfate is not intended for intravenous administration.

OVERDOSAGE

Due to limited experience in humans with overdosage of sucralfate, no specific treatment recommendations can be given. Acute oral studies in animals, however, using doses up to 12 g/kg body weight, could not find a lethal dose. Sucralfate is only minimally absorbed from the gastrointestinal tract. Risks associated with acute overdosage should, therefore, be minimal. In rare reports describing sucralfate overdose, most patients remained asymptomatic. Those few reports where adverse events were described included symptoms of dyspepsia, abdominal pain, nausea, and vomiting.

DOSAGE AND ADMINISTRATION

Active Duodenal Ulcer

The recommended adult oral dosage for duodenal ulcer is 1 g (10 mL/2 teaspoonfuls) four times per day. Sucralfate Suspension should be administered on an empty stomach.

Call your doctor for medical advice about side effects.

Antacids may be prescribed as needed for relief of pain but should not be taken within one-half hour before or after sucralfate.

While healing with sucralfate may occur during the first week or two, treatment should be continued for 4 to 8 weeks unless healing has been demonstrated by x-ray or endoscopic examination.

Elderly

In general, dose selection for an elderly patient should be cautious, usually starting at the low end of the dosing range, reflecting the greater frequency of decreased hepatic, renal, or cardiac function, and of concomitant disease or other drug therapy. (See PRECAUTIONS Geriatric Use)

You may report side effects to FDA at 1-800-FDA-1088.

HOW SUPPLIED

Sucralfate Suspension 1 g/10 mL is a pink suspension supplied in unit dose cups of 10 mL packaged in trays of 10, NDC 0121-0747-10.

SHAKE WELL BEFORE USING.

AVOID FREEZING.

Store at controlled room temperature 20°-25°C (68°-77°F) [see USP].

Manufactured by:
Sanofi-Aventis USA
Kansas City, MO 64137
for Axcan Pharma US, Inc.
Birmingham, AL 35242

Packaged by:
Pharmaceutical Associates, Inc.
Greenville, SC 29605

R09/09

PRINCIPAL DISPLAY PANEL - Bag

Sucralfate Suspension

1 g/10 mL

5 Cups

Y68

NDC 55154-9432-5

SUCRALFATE SUSPENSION 1 g/10 mL

5 CUPS

Delivers 10 mL

SHAKE WELL

See product insert for prescribing information, precautions and warnings.

STORAGE: Store at 20 to 25 C (68 to 77 F). [See USP Controlled Room Temperature]

RX ONLY

WARNING: This package is intended for institutional use only. Keep this and all drugs out of the reach of children.

Mfg. by: Sanofi-Aventis USA
Kansas City, MO 64137

Pkg. by: Pharmaceutical Associates, Inc.
Subsidiary of Beach Products, Inc.
201 Delaware Street
Greenville, SC 29605
(800) 845-8210
www.paipharma.com

DURA-DOSE is a trademark owned by its respective owner.

Repackaged by Cardinal Health
Zanesville, OH 43701
L37784461214

LOT #: XXXX

EXP. DATE: 12/34

SUCRALFATE

sucralfate suspension

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:55154-9432(NDC:0121-0747)
Route of Administration	ORAL	**DEA Schedule**	

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
Sucralfate (UNII: XX73205DH5) (Sucralfate - UNII:XX73205DH5)	Sucralfate	1 g in 10 mL

Inactive Ingredients	
Ingredient Name	**Strength**
SORBITOL (UNII: 506T60A25R)	

Product Characteristics			
Color	PINK	**Score**	
Shape		**Size**	
Flavor	CHERRY (maraschino)	**Imprint Code**	
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:55154-9432-5	5 in 1 BAG		
1		10 mL in 1 CUP, UNIT-DOSE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA019183	11/19/2009	

Labeler - Cardinal Health (188557102)

Establishment

Name	Address	ID/FEI	Business Operations
Cardinal Health		188557102	REPACK(55154-9432)